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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,489	02/21/2006	Matthew Scanlan	029065.51088US2	3837

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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,489	SCANLAN ET AL.	
	Examiner	Art Unit	
	Meera Natarajan Ph.D.	1609	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-19,21-23,25-31 and 33-47* is/are pending in the application.

4a) Of the above claim(s) *8,9,21-23,30,33,34 and 41-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,25-31 and 35-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/04/2006 and 02/05/2007*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-4, 6-7, 25-31, 35-47 and species elections: cytotoxic agents, calicheamicin, and SEQ ID No. 49 in the reply filed on 04/27/2007 is acknowledged. The traversal is on the ground(s) that all of the claims are linked by a single inventive concept: a substantially pure immunoglobulin molecule that binds specifically to the A34 antigen and uses thereof. Therefore, applicant argues a search of antibodies to the A34 antigen would necessarily uncover the art related to the uses of those antibodies. This is not found persuasive because the art applied in the restriction requirement (Nustad et al.) reads on the single inventive concept. Therefore the technical feature recited in claim 1 is not special and the groups are not so linked as to form a single general concept under PCT Rule 13.1. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-19, 21-23, 33, and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/27/2007.

3. Claim 30 and 41-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/27/2007.

4. Claims 1-4, 6-7, 25-31, and 35-47 will be examined on the merits.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicant discloses several hyperlinks on pages 24 and 26 of the specification that require correction.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 6 and 7 are drawn to a composition comprising a therapeutically effective amount of an immunoglobulin molecule which binds specifically to A34 antigen and is conjugated to an anti-cancer agent and at least one pharmaceutically acceptable carrier.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988);

and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The specifications provide working examples for using said immunoglobulin molecule which binds A34 to investigate the A34 protein *in vitro*. Applicant provides evidence for an intended diagnostic use by showing A34 protein expression in Esophageal carcinoma tissue whereas in normal esophageal tissue A34 was not present. However, Applicant does not provide evidence for a "therapeutically effective" use of the A34 immunoglobulin. The therapeutic example for "eliciting an immunoresponse against a tumor by stimulating ADCC and/or CDC responses and conjugating the A34 specific antibody with a radioisotope or a chemotherapeutic or cytotoxic agent for both therapeutic and/or diagnostic purposes" recited in the specifications on p. 37 section [00132] does not provide actual evidence that this intended use was successfully carried out. Therefore, the quantity of experimentation necessary, the amount of guidance needed, and the unpredictability of whether or not the intended therapeutic use would be "effective" would all require undue experimentation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and dependent claims 2-4, 6-7, 25-31 and 35-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al. (WO99/26972 June 1999). The claims recite a substantially pure immunoglobulin molecule which binds specifically to A34 amino acid sequence (SEQ ID NO:1). The WO99/26972 document teaches "compositions comprising an antibody which specifically reacts with such protein...provided by the present invention" (WO99/26972 p. 27 line 26-27). Jacobs et al. further discloses that the "protein of the invention may also be used to immunize animals to obtain polyclonal and monoclonal antibodies which specifically react with the protein. Such antibodies may be obtained using either the entire protein or fragments thereof as an immunogen" (p.73 last paragraph WO99/26972). The sequence of the isolated polypeptide molecule comprising A34 (SEQ ID NO: 2 of WO99/26972) is the same as Applicants' SEQ ID NO: 1 (Figure 3 as stated in the specifications, p.16). Therefore an antibody directed towards an antigen with SEQ ID NO: 2 of WO99/26972 would meets the limitations of an immunoglobulin molecule which binds specifically to A34 (SEQ ID NO:1) as recited in Claim 1, since both sequences are identical. (See attached sequence alignment)

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan Ph.D. whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

Mary Mosher

MARY MOSHER
SUPERVISORY PATENT EXAMINER
5-24-07